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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,869	12/21/2001	James Samsoondar	213202.00354	4454

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PATENT ADMINSTRATOR
KATTEN MUCHIN ZAVIS ROSENMAN
525 WEST MONROE STREET
SUITE 1600
CHICAGO, IL 60661-3693

EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,869	SAMSOONDAR, JAMES	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2004 and 21 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *67,69,70,73,79,80,82 and 98-101* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67,69,70,73,79,80,82 and 98-101* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/147,373.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 67, 69-70, 73, 79-80, 82 and 98-101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On the last two lines of claim 67, the phrase "the quality control material being stabilized" is indefinite since the conditions of stabilization have not been recited. In other words, it is not clear how the quality control material is stabilized and under what conditions it is stabilized (i.e. temperature, light, atmosphere, etc). The stabilization of a reagent is relative to the conditions under which it is stabilized. The instant specification does not further define "stabilized" since page 22 of the specification only states that the control material is "stable under storage and measurement conditions", but does not recite what those conditions are. Any reagent can be stable under certain controlled conditions. In addition, page 42 of the instant specification only states that preservatives may be added to the control material, and that the material may be stored under any suitable temperature. Therefore, the specification does nothing to further define what "stabilized" means.

Claim 67 is also indefinite since it recites that the sample can be one of cottage cheese, milk, ice cream, yogurt, cheese, wine, beverages, semi-solid foods and soft solid foods. The dependent claims recite that the analyte being mimicked in the sample can be an indicator of hemolysis such as total Hb, oxy-Hb and total Hb minus met-Hb. It is not understood how one of the recited types of hemoglobin can be present in a sample such as cheese, yogurt, cottage cheese, ice cream etc. since hemoglobin results from the lysis of red blood cells containing hemoglobin therein, and foods such as cottage cheese, yogurt, ice cream, etc do not contain

blood having red blood cells therein. There is an inconsistency between the recited sample types and the analytes found in these samples among all of the claims.

On line 3 of claim 79, there is a typographical error in the phrase "wherein said two or more analytes area selected".

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 67, 69-70, 73, 79-80 and 100 are rejected under 35 U.S.C. 102(b) as being anticipated by either patent to Jacobs et al (either US Patent no. 5,846,492, submitted in the Information Disclosure Statement filed on May 30, 2002 or US Patent no. 6,013,528).

Both patents to Jacobs et al teach of calibrator liquids for spectrophotometric analysis, which contain known amounts of hemoglobin, Intralipid and biliverdin in a human serum matrix. Intralipid serves to mimic turbidity in a blood sample. See lines 26-35 in column 8 and table 1 in Jacobs et al ('528), and lines 48-56 in column 8 and table 1 in Jacobs et al ('492). In this embodiment, there is no bilirubin present in the calibrator solutions. In a second embodiment taught by both patents to Jacobs et al, there is bilirubin present in the calibrator solutions. See lines 32-60 in column 10 of the '492 patent, and lines 10-38 in column 10 of the '528 patent. The calibrator solutions are exposed to atmospheric conditions since Jacobs et al teach that the

solutions are prepared in an open sample vessel, and then aspirated by a probe into an analyzer. Since the instant claims recite new matter (i.e. a perfluorocarbon-like blood substitute, a hemoglobin-based blood substitute, exposure to atmospheric conditions, etc) that is not present in the parent application (serial no. 09/147,373), the effective filing date of the instant application is December 21, 2001. Therefore, both patents to Jacobs et al qualify as prior art under 35 USC 102(b).

4. Claims 67, 73, 79 and 100 are rejected under 35 U.S.C. 102(e) as being anticipated by Jacobs et al (US 2003/0068822, submitted in the Information Disclosure Statement filed on June 9, 2003).

Jacobs et al teach of a control solution for a hemoglobin assay, which comprises an indicator of hemolysis. The indicator is a cross-linked blood substitute, preferably one known under the tradename OXYGLOBIN. This blood substitute product has similar spectrophotometric characteristics as hemoglobin-containing fractions of hemolysed blood. There is no bilirubin in the control solution, and the solution is exposed to atmospheric conditions since Jacobs et al teach that it is prepared in an open sample vessel, and then measured by an analyzer. Since the instant claims recite new matter (i.e. a perfluorocarbon-like blood substitute, a hemoglobin-based blood substitute, exposure to atmospheric conditions, etc) that is not present in the parent application (serial no. 09/147,373), the effective filing date of the instant application is December 21, 2001. Therefore, the publication to Jacobs et al qualifies as prior art under 35 USC 102(e).

5. Applicant's arguments filed March 26, 2004 have been fully considered but they are not persuasive.

The new declaration received on April 21, 2004 is acceptable. The previous objections to the abstract and specification made in the last Office action mailed on February 2, 2004 are withdrawn in view of Applicant's amendments to these sections of the application. The previous rejections of the claims under 35 USC 112, second paragraph are also withdrawn in view of Applicant's amendments thereto. However, new rejections of the amended claims under this statute are set forth above, as necessitated by Applicant's amendments to the claims. The previous double patenting rejection made in the last Office action is also withdrawn in view of the appropriately filed terminal disclaimer. The previous rejections of the claims under 35 USC 102(b) as being anticipated by Campbell et al, Grandjean, Artiss et al and Sorensen et al are withdrawn in view of Applicant's amendments to the claims and persuasive arguments.

With regards to the rejection of the claims under 35 USC 102(b) as being anticipated by either patent to Jacobs et al (5,846,492 and 6,013,528), Applicant argues that the calibrator materials taught by Jacobs et al do not mimic analytes in a sample as claimed since the materials disclosed by Jacobs et al contain the analytes used to develop calibration algorithms. In response to this argument, it is noted that the calibration material taught by Jacobs et al contains one or more substances (i.e. hemoglobin, Intralipid and biliverdin) that mimic two or more analytes in a sample such as a human serum. The two or more analytes can be hemoglobin, turbidity and biliverdin. Since independent claim 67 does not recite that the one or more substances cannot mimic themselves, the teaching of Jacobs et al anticipates this claim. Applicant also argues that the substances used in the calibrator materials of Jacobs et al have a short shelf life, rather than the long shelf life of months and years of the claimed invention. In response to this argument, it is noted that the instant claims do not recite how long the quality control material is stable, and

fail to define the conditions of stabilization as noted above in the rejection under 35 USC 112, second paragraph. In addition, it also is not clear where in the Jacobs' et al patents that it is taught that the calibrator materials have a short shelf life.

With regards to the rejection of the claims under 35 USC 102(e) as being anticipated by Jacobs et al (US 2003/0068822), Applicant argues that Jacobs et al only teaches of one substance, a cross-linked blood substitute, that mimics one analyte, rather that one or more substances that mimic two or more analytes as set forth in the instant claims. In response to this argument, it is noted that Jacobs et al teach that other substances can be present in the control solution in addition to the cross-linked blood substitute that mimics hemoglobin. See paragraph no. 16 on page 2 of Jacobs et al. Since the instant claims do not recite that the one or more substances cannot mimic themselves, the teaching of Jacobs et al that other analytes could be present in the control solution, such as biliverdin, Intralipid, etc. anticipates the instant claims as presently written.

For the above reasons, not all of Applicant's arguments are found persuasive.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

June 1, 2004

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700